

AD_____

Award Number: W81XWH-10-1-0889

TITLE:

Biomarkers for Autism and for Gastrointestinal and Sleep Problems in Autism

PRINCIPAL INVESTIGATOR: George M. Anderson, Ph.D.

CONTRACTING ORGANIZATION: Yale University
New Haven, CT 06520-8047

REPORT DATE: December 2014

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

☒ Approved for public release; distribution

unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE December 2014		2. REPORT TYPE Final		3. DATES COVERED (30Sep2010 - 29Sep2014)	
4. TITLE AND SUBTITLE Biomarkers for Autism and for Gastrointestinal and Sleep Problems in Autism					
				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-10-1-0889	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) George M. Anderson email: george.anderson@yale.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Yale University 47 College Street, Suite 203 PO Box 208047 New Haven, CT 06520-8047 Phone: 203-785-4689 Email: gcat1@yale.edu				8. PERFORMING ORGANIZATION REPORT	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT Sample collection has now been completed and final biochemical analysis are underway and expected to be completed by March 31, 2015. Data analysis and presentation of results are planned for 2015. At this time we are requesting an extension of the date for the submission of the Final Report to December 31, 2015 so that the findings and presentations of the study can be described.					
15. SUBJECT TERMS URINARY MELATONIN, TODDLERS, AUTISM, SLEEP, gastrointestinal					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 4	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

Standard Form 298 (Rev. 8-98)

Table of Contents

	<u>Page</u>
Table of Contents.....	3
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	4
Reportable Outcomes.....	4
Conclusion.....	4
References.....	4
Appendices.....	4

Introduction

The objective of the proposed research is to compare the production of melatonin by young children with autism (N=45) to typically developing children (N=45). Specifically, we will see if the nighttime excretion rate of melatonin sulfate is markedly lower in the children with autism, whether there is a subgroup of children with autism having very low excretion; whether low nighttime excretion of melatonin sulfate is associated with sleep problems; and whether low daytime melatonin sulfate excretion is associated with gastrointestinal problems.

Keywords

urinary melatonin, toddlers, autism, sleep, gastrointestinal

Overall Project Summary

Problems with recruitment led to the need to extend the study past the original end date of September 30, 2013. A request for a no-cost extension was granted through September 30, 2014 in order that original total recruitment targets could be reached. The total recruitment target of 45 ASD individuals has now been reached. Sample collection has now been completed and final biochemical analysis are underway and expected to be completed by March, 2015. Data analysis and presentation of results are planned for 2015. The study has been re-approved by the Yale Human Investigation Committee through October 10, 2015. At this time we are requesting an extension of the date for the submission of the Final Report so that the findings of the study and presentations of the results can be described. A final post-completion report will be submitted to the U.S. Army Medical Research and Materiel Command by December 31, 2015.

Key Research Accomplishments

None to date (see above)

Conclusions

None to date (see above)

Publications, Abstracts and Presentations

None to date (see above)

Inventions, Patents and Licenses

None to date (see above)

Reportable Outcomes

None to date (see above)

Other Achievements

None to date (see above)

References

None to date (see above)

Appendices None